

Aventis CropScience



U.S. EPA
Enforcement and Compliance Docket and Information Center
Mail Code 2201A
ATTN: Docket No. EC-2000-007
1200 Pennsylvania Avenue, N.W.
4th Floor, Room 4033
Washington, D.C. 20004

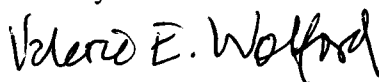
Date: February 25, 2002

Please note:

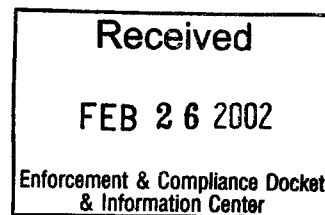
The first time I submitted our comments (last Thursday), the UPS delivery was refused because there was no suite/room number.

Since our original comments document still has not been returned to us by UPS, please accept the attached photocopy of the original as our comments.

Thank you.



Valerie E. Wolford
Documentation Services
Regulatory Affairs



Aventis CropScience



February 20, 2002

United States Environmental Protection Agency
Enforcement and Compliance Docket and Information Center
Mail Code 2201A
ATTN: Docket Number EC-2000-007
1200 Pennsylvania Avenue N.W.
Washington, D.C. 20460

Re: Comments on CROMERRR, EC-2000-007

Aventis CropScience USA LP (Aventis CropScience) is submitting the following comments relating to EPA's proposed regulation, Cross-Media Electronic Reporting and Records Rule (CROMERRR), 66 FR 46162, dated August 31, 2001.

We have reviewed the requirements of the proposed regulations to better understand and assess their impacts on existing recordkeeping and data reporting processes in place in companies affected by the proposed regulations. We hereby submit comments to EPA as part of the public commenting process of this proposed rule-making.

EPA has asked for comments on several questions related to the proposed CROMERRR. One of these is "whether or not the recordkeeping provisions...should be withdrawn and addressed in a separate rulemaking." After a detailed examination of the proposed Rule, Aventis CropScience recommends that the recordkeeping provisions be withdrawn.

In addition, Aventis CropScience also believes that parties affected by the proposed CROMERRR have been obliged to devote virtually the entire commenting period to evaluation of the recordkeeping portions of CROMERRR. Because of this, Aventis CropScience recommends and requests that EPA provide an additional time of 60 days beyond the existing commenting deadline to allow commenters to examine more fully the electronic reporting provisions of the proposed rule. We strongly believe that during this additional commenting period EPA should hold public meetings focused solely on the reporting provisions (as EPA has done with the recordkeeping portions in its recent public meetings) to afford the dialogue that is necessary for the Agency to make an informed evaluation of the potential impact of these provisions.

Withdrawal of recordkeeping provisions

The main reasons for our recommendation to withdraw the recordkeeping provisions of CROMERRR are as follows:

- The electronic recordkeeping provisions would be mandatory, not voluntary, and they would be contrary to some provisions of the Government Paperwork Elimination Act (GPEA)
- Costs of compliance with CROMERRR as it is currently written have been dramatically underestimated by EPA, and would represent a financial and practical burden that is unprecedented and unwarranted

- CROMERRR would create disincentives for global harmonization among government regulatory authorities

- 1) Electronic recordkeeping provisions not “voluntary” - The CROMERRR preamble states that “Under today’s proposal, electronic document submission or electronic recordkeeping will be totally voluntary....” The proposed Rule states that an entity can choose to keep records electronically or in paper, but that entities maintaining records electronically will be subject to compliance with CROMERRR. Aventis CropScience believes the assertion that “electronic recordkeeping is totally voluntary” is misleading and unrealistic, and that in fact, for the majority of regulated entities, compliance with CROMERRR would be mandatory. Due to the state of modern technology, most regulated entities are already maintaining records that are partially or wholly electronic. Aventis CropScience maintains that it would be difficult, and perhaps impossible, to maintain intellectual property that is totally paper-based; therefore, this portion of the CROMERRR rule appears to be mandatory.

Applying CROMERRR in its current version, the Rule would apply to any EPA-mandated data captured or maintained on a computerized system, and the printing out of that data for the purpose of record retention would not be permitted. Therefore, the electronic recordkeeping portion of CROMERRR would be mandatory for agricultural chemical companies, because they use electronic capture systems in the laboratory and in the field in support of EPA-regulated pesticide registrations.

Regulatory Flexibility Analysis – EPA opted not to conduct a Regulatory Flexibility Analysis (RFA) of CROMERRR based on its assessment that electronic recordkeeping and reporting, as described in the proposed Rule, is voluntary. However, since virtually all small businesses subject to EPA recordkeeping requirements collect and keep at least some data electronically in order to comply, many would be subject to CROMERRR. Therefore Aventis CropScience maintains that an RFA of CROMERRR is needed to estimate the financial burden imposed on Small Business.

Contract Laboratories:

Aventis CropScience and many other companies in the crop-protection industry frequently utilize consultants and contractors to provide support for permit applications, process design, analytical services, etc. Often outside services are used due to specialized equipment, knowledge base or intellectual property. We do not control or have access to the computers, databases, or technology and therefore could not ensure that these systems are maintained and the information is archived as described in CROMERRR. Consultants frequently use sub-contractors on larger projects. We have very little ability to control or influence electronic data controlled by this group. Aventis CropScience does not believe it is realistic to expect companies to be able to guarantee that equipment calibration records at a contract analytical lab are maintained for a period of 20+ years.

Recordkeeping provisions would be contrary to some provisions of Government Paperwork Elimination Act (GPEA) – CROMERRR would impose a greater compliance burden with regard to electronic, versus paper records. For example, in the case of electronic recordkeeping, CROMERRR would require the establishment and archiving of metadata including audit trails (unlike paper records), and prohibit the purging of electronic records after conversion to another medium, such as microforms or paper (unlike paper records).

Office of Management and Budget (OMB) recognized that agencies would be tempted to impose anti-fraud provisions in implementing GPEA. In its GPEA implementation guidance OMB warned against the kind of extreme provisions found in CROMERRR:

"Setting up a very secure, but expensive, automated system may in fact buy only a marginal benefit of deterrence or risk reduction over other alternatives and may not be worth the extra cost. For example, past experience with fraud risks, and a careful analysis of those risks, shows that exposure is often low. If this is the case a less expensive system that substantially deters fraud is warranted, and not an absolutely secure system."¹

CROMERRR calls for an absolutely secure electronic system. It sets forth a one set of requirements for all EPA-mandated recordkeeping, regardless of the risk of fraud. OMB specifically cautioned against this "one-size-fits-all" approach:

"Agencies should also keep in mind that GPEA specifically states that electronic records and their related electronic signatures are not to be denied legal effect, validity, or enforceability merely because they are in electronic form. We are not, therefore, prescribing "one size fits all" requirements applicable to transactions regardless of their sensitivity."²

Thus, the CROMERRR recordkeeping provisions would be contrary to both GPEA and OMB's guidance on implementing GPEA.

- 2) Costs of compliance with CROMERRR have been underestimated by EPA - Aventis CropScience believes that ICR No. 2002.02 does not accurately reflect the costs associated with implementing CROMERRR electronic recordkeeping requirements, especially given the extensive number of legacy systems which would require significant upgrades. The \$40,000 cost (in capital and manpower) estimated by EPA to implement an individual recordkeeping system is well below the cost of many data collection systems and systems with the capabilities required for compliance with CROMERRR. Based on experience with implementing systems to fulfill FDA's 21 CFR Part 11 electronic recordkeeping requirements (which CROMERRR uses as a model for its requirements), some companies in our industry estimate that these costs would actually approach or exceed \$900,000 per facility. (These costs include the direct purchase price and license fees for supporting hardware and software, validation and documentation, training, and labor costs for implementation.)

Costs to upgrade data collection systems at individual research and testing laboratories would be proportionately greater, given the instrument-intensive environments and the more pervasive use of computer-mediated control and data collection and handling, along with the higher number of supported users, which exist at these facilities.

All legacy computerized systems affected would have to be retrofitted with software (and perhaps additional hardware) to meet CROMERRR requirements, or new systems would have to be purchased to comply. In many field and laboratory situations, certified systems to meet the proposed recordkeeping requirements do not exist.

There is no good solution for fulfilling CROMERRR requirements for retaining electronic data for the length of the currently specified retention schedules. Record retention of electronic records for 20-30-50-75 years will be very costly and require multiple migrations to ensure electronic accessibility. EPA has not presented a realistic picture to the regulated parties of these costs for compliance. The Agency should consider re-evaluating their required retention schedules, or provide the option to maintain data in alternate

¹ 65 Fed. Reg. at 25515 (emphasis added).

² 65 Fed. Reg. at 25510 (emphasis added).

media, when complete data migration is not feasible. Maintaining retired equipment, in order to retrieve data in human-readable form for the current required retention schedules, is not a viable option.

Complete migration of instrument raw data is not technically possible. Some data (3-5%) is always going to be lost or not used because the new system may not be set up to accommodate it. Over several migrations, the amount of data loss would be substantial.

The electronic records to be archived are not well defined in CROMERRR. Besides study specific data, other records required for GLP compliance such as master schedules, SOPs, personnel records would also potentially be included in the proposed recordkeeping requirements.

Much of the raw data collected for environmental monitoring is aggregated or compressed prior to archiving. The volume of data captured for environmental monitoring would be in many cases impossible to maintain in its original form. Archiving requirements for FIFRA extend for the life of registration (decades) and far exceed demands of FDA's 21 CFR Part 11.

The additional and very large costs of long-term storage, retrieval and migration of data to new media, and systems validation that CROMERRR implies, present an unwarranted and undue burden particularly since significant and comprehensive data-integrity-protection measures are already in effect at companies such as Aventis CropScience.

- 3) CROMERRR would create disincentives for harmonization – Aventis CropScience is working with national regulatory agencies in various forums to bring data requirements and registration decision-making processes into harmony. The proposed CROMERRR rule would establish electronic recordkeeping requirements more restrictive than those currently existing under EU and OECD guidelines, establishing a unique standard at a time when more and more countries are striving to harmonize their regulatory approaches.

OECD GLP guidelines allow for definition of "raw data" for each computerized system to include computer or instrument printouts. Therefore, OECD allows flexibility in the definition and retention of raw data. The OECD "Application of the Principles of GLP to Computerized Systems", Monograph No. 116, Section 5, indicates "Computerized systems operating in compliance with GLP Principles may be associated with raw data in a variety of forms, for example, electronic storage media, computer or instrument printouts and microfilm/fiche. It is necessary that raw data are defined for each computerized system."

Section 5 also states, "where system obsolescence forces a need to transfer electronic raw data from one system to another then the process must be well documented and its integrity verified. Where such migration is not practicable then the raw data must be transferred to another medium and this verified as an exact copy prior to any destruction of the original electronic records."

Governmental efforts over the past years have been to harmonize GLP requirements globally. The new recordkeeping requirements proposed in CROMERRR would conflict with EPA's current practice of accepting OECD GLP guideline studies.

Reporting Provisions

As stated earlier in these comments, Aventis CropScience is very concerned that the troubling aspects of the proposed recordkeeping provisions have made it necessary for commenters to focus nearly all their

time on evaluation of those provisions, thus preventing an adequate evaluation of the implications of the reporting provisions. Indeed, the proposed recordkeeping provisions have caused so much concern that the public meetings held to date have focused on these provisions almost exclusively (in some cases even by mandate of EPA via the limiting of the scope the 2002 public meetings to only recordkeeping provisions). This focus on the recordkeeping provisions has been at the expense of a considered look at, and dialogue on, the reporting provisions.

A preliminary evaluation of CROMERRR's reporting provisions has caused concern at Aventis CropScience and others in our industry. For example, CROMERRR states that "Accordingly, once this rule takes effect, documents subject to this rule submitted directly to EPA can only be submitted electronically after EPA announces in the Federal Register that the Central Data Exchange (CDX) or an alternative system is ready to receive them." What is considered a 'document' is ill-defined in CROMERRR; therefore, since Aventis CropScience already submits some environmental-monitoring and other data electronically to EPA, the possibility exists that pending acceptance of electronic reporting of this data under CROMERRR, non-compliance could be created as soon as CROMERRR becomes a final rule. In addition the provisions for acceptance and maintenance of electronic signatures appear to propose significant and unwarranted burdens given that alternate schemes for electronic signatures (ex.: E-Sign), which provide verifiable and acceptable levels of security controls, already exist.

We believe that additional time is needed to allow for full evaluation of this piece of the proposed rule and that during this period EPA should hold public meetings whose scope focus solely on the reporting provisions.

In summary, Aventis CropScience believes that the proposed recordkeeping provisions of CROMERRR should be withdrawn in their entirety. The costs that these provisions imply have been dramatically underestimated by EPA, would pose an unwarranted and far-reaching burden, and create international harmonization disincentives. We further strongly request that an additional commenting period of 60 days beyond February 27, 2002 be provided to allow for full examination of the reporting provisions of CROMERRR and for public meetings focusing on these provisions.

Thank you for the opportunity to comment on this proposed rule.

Respectfully submitted,

A handwritten signature in black ink, reading "Margaret Cherny". The signature is fluid and cursive, with the first name and last name clearly distinguishable.

Margaret A. Cherny

Vice President, Communications and Government Relations